K063769

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510(K) SUMMARY

Alpha-Bio Tec® Bone Fixation Screw System

510(k) Number K_____

A. Applicant's Name: Alpha-Bio Tec Ltd
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B. Contact Person: Daniela Ben Shabat
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e-mail: Daniela@alpha-bio.net
Web site: www.alpha-bio.net

C. Date Prepared: March 2006

D. Trade Name: Alpha-Bio Tec®

E. Classification: **Name**: Screw, Fixation, Intraosseous
Product Code: DZL
Regulation No: 872.4880
Class: II
Panel: Dental

F. Predicate Devices: The Alpha-Bio Bone Fixation Screw System is substantially equivalent to Straumann K050515; K011698; in terms of intended use, indications for use, technological characteristics, performance and user interface.

The predicate device is Class II medical devices.

A discussion of substantial equivalence is provided in Section 3 of this submission.

G. Device Description: The Alpha-Bio Bone Fixation Screw System consists of titanium alloy Gr-5 screws with 1.2mmd and 1.6mmd diameter, and with 4mm-12mm lengths. This system includes drill instrument for fixating the screw to the bone in the oral cavity at regeneration procedure

H. Intended Use / Indication for Use: The Alpha-Bio Bone Fixation Screw System is indicated for stabilize and fixate bone grafts, bone filling materials, and / or barrier membranes used for regeneration of bone in the oral cavity. The system includes titanium screws 1.2mmd and 1.6mmd diameter, and drill instrument for fixating the screw to the bone in the oral cavity at regeneration procedure.

I. Performance Standards: No performance standards have been established for such devices under Section 514 of the Federal Food, Drug, and Cosmetic Act.

The device complies with the following recognized standards:

- ISO 7405:1997, Dentistry - Preclinical Evaluation of Biocompatibility of Medical Devices Used in Dentistry - Test Methods for Dental
- F136–02a: 2004 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).
- ASTM F1350-02, 2002 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673).
- ISO 13402:1995, Surgical and dental hand instruments - - Determination of resistance against autoclaving, corrosion and thermal exposure.
- UL 544 (1998):, Standard for Medical and Dental Equipment - Ed. 4.0.

J. Substantial Equivalence: There are no unique applications, indications, materials or specifications presented below. Evidence of equivalence has been demonstrated through:

- The Alpha-Bio Tec® intended use and indications for use were previously cleared by FDA for the predicate device.
- The technical characteristics of the Alpha-Bio Tec® are similar to those of the predicate device.
- Safety and performance testing.

Therefore, the Alpha-Bio Tec® is substantially equivalent to its predicate devices as cited above and raises no new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alpha-Bio Tec Limited
C/O Mr. Daniel J. Manelli
Attorney
Manelli & Fisher, P.L.L.C.
5335 Wisconsin Avenue, NW Suite 440
Washington, DC 20015

MAR 3 0 2007

Re: K063769
Trade/Device Name: Alpha Bio Tec® Bone Fixation Screw System
Regulation Number: 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: December 19, 2006
Received: December 20, 2006

Dear Mr. Manelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K063769

Device Name: Alpha Bio Tec® Bone Fixation Screw System

Indications for Use:

The Alpha-Bio Bone Fixation Screw System® is used to stabilize and fixate bone grafts, bone filling materials, and / or barrier membranes used for regeneration of bone in the oral cavity. The system includes titanium screws 1.2mmd and 1.6mmd diameter, and drill instrument for fixating the screw to the bone in the oral cavity at regeneration procedure.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...ion of Anesthesiology, General Hospital,
...ection Control, Dental Devices

510(k) Number: K063769